

PCT

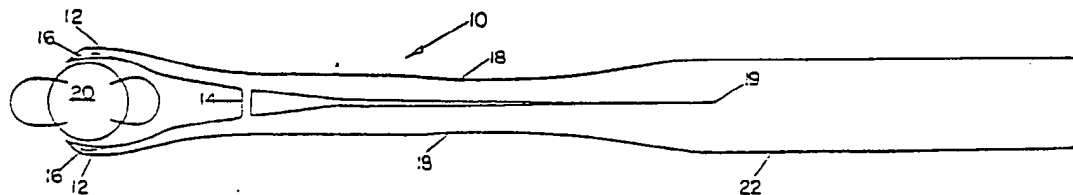
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ³ : A61B 17/30	A1	(11) International Publication Number: WO 82/ 01646 (43) International Publication Date: 27 May 1982 (27.05.82)
(21) International Application Number: PCT/US81/01509 (22) International Filing Date: 12 November 1981 (12.11.81) (31) Priority Application Number: 206,488 (32) Priority Date: 13 November 1980 (13.11.80) (33) Priority Country: US (71)(72) Applicants and Inventors: LeVEEN, Harry, H. [US/US]; RUBRICIUS, Jeanette, L. [US/US]; 321 Confederate Circle, Charleston, SC 29407 (US). (74) Agents: HALE, John, S. et al.; 1925 North Lynn Street, Suite 905, Rosslyn, VA 22209 (US).		(81) Designated States: AT (European patent), AU, BR, CH (European patent), DE (European patent), FR (European patent), GB (European patent), JP, LU (European patent), NL, NL (European patent), SE (European patent). Published <i>With international search report.</i>

(54) Title: INTRAOCULAR LENS FORCEPS



(57) Abstract

An intraocular lens holder of one piece construction comprising a pair of jaws (12), a fulcrum (14) and a handle (22), the jaws (12) and handle (22) being constructed at an acute angle to facilitate surgery. The jaws are slotted to hold the periphery of an intraocular lens without pressure and extend to and beyond the fulcrum (14) to form the handle (22). The two jaw extensions (18) or handle may be pressed together by the surgeon to open the jaws (12) and release the lens and contact of the two handle extensions (18) signals the surgeon that the jaws (12) have opened to release the lens preventing unnecessarily broad excursion of the jaws (12) which may damage the interior of the eye.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	KP	Democratic People's Republic of Korea
AU	Australia	LI	Liechtenstein
BR	Brazil	LU	Luxembourg
CF	Central African Republic	MC	Monaco
CG	Congo	MG	Madagascar
CH	Switzerland	MY	Malawi
CM	Cameroun	NL	Netherlands
DE	Germany Federal Republic of	NO	Norway
DK	Denmark	RO	Romania
FI	Finland	SE	Sweden
FR	France	SN	Senegal
GA	Gabon	SL	Soviet Union
GB	United Kingdom	TD	Chad
HL	Hungary	TG	Togo
JP	Japan	US	United States of America

- 1 -

INTRAOCULAR LENS FORCEPSBackground of the Invention

The condition of lenticular opacity in the eye, known as a cataract, is a leading cause of blindness and is especially common among the elderly. The primary means of alleviating a cataract is to remove the diseased natural lens, and more than 400,000 persons in the United States undergo surgery for removal of clouded lenses in eyes each year.

When no lens is present in the eye, which is known as an aphakic condition or aphakia and is usually the result of intracapsular or extracapsular lens extraction, the eye does not have the ability to focus rays of light. Therefore, the eye receives a blurred image and vision is severely impaired.

The most common solution for providing a focusing mechanism to obviate the aphakic condition is to interpose contact lenses or spectacles or a combination thereof between the eye and the light entering therein. However, both contact lenses and spectacles have drawbacks when used in the treatment of aphakia. Neither spectacles nor contact lenses can duplicate the natural optical system because they are positioned outside of the eye, which results in a shift of the optical center from the vivo state. Because the optical center has been shifted, the image received by the eye is changed in size.

Many aphakia patients who have had their cataracts removed are fitted with glasses or spectacles. These thick lenses present many more problems than they solve. Immediately upon receiving cataract spectacles a patient is confronted with several problems in that there is significant increase in the size and shape of familiar objects and straight lines are formed into curves.

Contact lenses are superior to thick cataract spectacles since the wearer enjoys good peripheral vision.



- 2 -

The magnification problem does not bother contact lens wearers as much as it does cataract spectacle wearers, because the contact lenses only magnify in the range of 7 to 10 percent. Furthermore, hand to eye coordination of contact lens wearers is better than in spectacle wearers, as objects are seen in more normal spatial orientation and straight lines are not seen as curves. However, contact lenses are very small and fragile, and it is difficult to insert and remove them daily, particularly for elderly users or individuals with arthritis or coordination problems. In addition allergies and dry eye conditions also interfere with contact lens wearing.

The most promising method of sight restoration for cataract patients is the intraocular lens. An intraocular lens (hereinafter sometimes referred to as an IOL in various parts of the specification) is one which is placed inside the eye. When an IOL is implanted in substantially the same location formerly occupied by the natural lens, relatively normal vision may be restored to the patient. Generally lens implantation and cataract surgery takes around 45 minutes to an hour and with the lens implant the person usually has improved vision within a couple of days, and continued improvement over several more weeks until the eye is completely healed.

Intraocular lenses provide a significant improvement over the previously used artificial ocular aids in that once the implantation has been implemented patients regain a close approximation of their former visual function. The wearers of intraocular lens implants regain full side to side vision and problems of magnification and depth perception are practically non-existent. Since the intraocular lenses are permanently implanted within the eye, problems of daily cleaning, insertion and removal, and loss and replacement are eliminated. Furthermore,

- 3 -

the wearer can enjoy sports such as swimming as the lenses remain in the eye and cosmetically there is no difference between persons who have intraocular lenses and those persons who have had no history of cataracts or eye surgery.

5 Examples of lenses which are placed in the anterior chamber and are secured to the iris by various methods are shown in United States Patent Nos. 3,673,611; 3,906,551; 3,922,728; 3,925,825; 3,971,073; 3,975,779; 3,979,780; 3,986,214; 3,996,627; 4,010,496; 4,056,855; 10 4,073,015; 4,077,071; 4,079,470; and 4,087,866.

 Artificial lenses designed for positioning in the posterior chamber are described in United States Patent Nos. 3,711,870 and 4,014,049. The lenses disclosed in these patents comprise a central optical element surrounded by a resilient silicone flange shaped to receive 15 and nest against the ciliary body. The lenses are held in place by suturing the resilient flange to the ciliary body. Another lens shown in U.S. Patent Nos. 3,925,835 and 4,014,089 is designed for implantation in either 20 the anterior or posterior chamber of the eye, with the lens supporting (haptic) section of the IOL comprising a plurality of flexible spring like members designed to follow the margin of the dynamic pupil, while providing longitudinal fixation and centration of the lens. Patent 25 Nos. 4,053,953 and 3,866,249 disclose a posterior lens held in place by an insertion necklace in the former and a holding ring in the latter. In U. S. Patent No. 4,041,552 the lens element is placed in the posterior chamber and supported by support on the anterior side 30 of the iris, while a lower arm is sutured to the ciliary body and sclera at one side of the iris with another arm extending to the opposite side.

 U.S. Patent No. 3,913,143 discloses a lens apparatus inserted in the posterior chamber, with a plurality



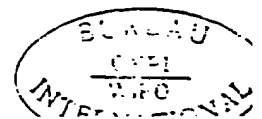
- 4 -

of cantilevered clips, each of which is mounted to a central portion which extends outward from the face of the lens towards the periphery. The clips are used to secure the iris to the front face of the lens when the lens is positioned within the posterior chamber of the eye behind the iris.

Various lenses are discussed in an article by D. P. Choyce entitled "History of Intraocular Implants" which is printed in Annals of Ophthalmology, October 1973. The article also includes a list of references from which further information concerning prior art intraocular lenses can be obtained. The aforementioned prior art lenses represent typical lenses which can be used in the present lens holding apparatus.

In the performance of intraocular lens implantation surgery, it is of course necessary to place and orient the delicate plastic lens accurately at the implantation site. Typically, each intraocular lens is less than half the diameter of a contact lens and is correspondingly lighter and flimsier. Like contact lenses and spectacles, an intraocular lens may be subject to scratching of its surface which degrades its optical qualities, but unlike exterior lenses, the intraocular lens is not easily replaced when damaged.

An example of a lens holder for contact lenses in the prior art is found in United States Patent No. 3,063,083. In this reference, the lens holder is used for immersing a contact lens in cleaning fluid. The jaws of the lens holder are lined with radial protuberances arranged in pairs spaced intermittently about the edges of the lens within the jaws. The circumference of the lens rests on the protuberances so that the periphery of the lens is separated from the jaws by clearance spaces. Thus, the minimal contact of the lens holder with the



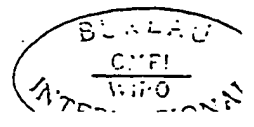
- 5 -

lens allows the greatest amount of lens surface area to come into contact with the cleaning fluid. However, if this device were scaled down to a size appropriate to an intraocular lens, the jaws would be spaced further away from the lens than is appropriate for a firm grip on the lens and a minimal surgical incision length on the eye.

United States Patent No. 3,817,078 discloses a wound clip removal device with jaws biased in a partly open positioned. The jaws may be opened further by placing pressure on two bowed handle portions which flex the jaws open.

Other patents of interest in the field of small clamping devices include United States Patent Nos. 1,521,689; 1,748,765; 2,222,744; 2,477,446; 2,595,683; 2,943,521; 3,063,083; 3,265,068; 3,650,008; 3,677,112; 3,817,078; 3,977,410; and 4,044,771. These devices share the deficiencies of numerous sharp and abrasive surfaces and a lack of adaptation for the particular nature of intraocular lenses.

Therefore, there is a clear need in the art for a means to hold an intraocular lens during surgery which will allow a lens to be oriented properly and accurately positioned either anterior or posterior to the iris, and which will hold the lens securely, yet without excess pressure which may damage the lens. The lenses generally have small loops which must be maneuvered to engage them into proper position. The lens holder should firmly grasp the lens but not continuously squeeze it since pressure can induce a creep into plastic lens material which will distort the optical qualities of the lens. In addition, since there is little room in the anterior chamber to manipulate a lens, the neck of the inserting device must be kept small. Further, the holding means



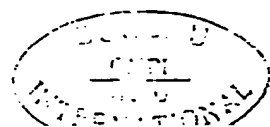
- 6 -

should maintain a constant grasp on the lens during manipulation by the physician, because small differences in tension and motion may result in dropping the lens onto an unsterile surface or a surface which scratches the lens or even losing grasp of the lens at a critical moment of implantation. Ordinary forceps have the disadvantage of requiring finger pressure to hold the lens, and movement of the jaws is magnified as compared to the movement of the compressing fingers. The lens holder should also be strong, light and of small dimensions so that it is easy to manipulate yet not so large as to require broad incision into the eye.

Summary of the Invention

In accordance with the present invention, there is provided an intraocular lens holder comprising a pair of jaws, a fulcrum and a handle. The pair of jaws are spaced apart a distance slightly less than the diameter of the lens to be held, and the surfaces of the jaws which face each other are slotted lengthwise so that when the jaws are in their normal position, a lens may be retained within the slotted faces without pressure and with evenly distributed stress placed on the lens. The neck of the holder is flattened in the same plane as the lens so that both may be inserted through a small surgical incision without difficulty.

The fulcrum of the invention comprises a small cross piece extending between the two jaws and behind the slotted jaw surfaces in which the lens is held. The jaws extend beyond the fulcrum to form a handle, and the extension of the jaws eventually unite at a point well beyond the fulcrum. The jaws and the handle meet at the fulcrum at an angle to each other to allow placement of the lens without either prying the cornea or the iris during its insertion.



- 7 -

When the lens is placed at the implantation site, it may be released from the jaws by squeezing the extensions of the jaws behind the fulcrum. The jaws are forced apart through the action of the fulcrum allowing removal of the holder from the surgical site, leaving the lens behind.

The present invention may be made of one-piece disposable semi-rigid plastic or other smooth lightweight material, and has no jagged edges or surfaces to interfere with manipulation by the physician or to damage the eye or the lens itself. Being of one-piece construction, the present invention also offers the advantage of having no delicate small separable parts to lose or be dropped within or without the eye.

Typically, the present invention will be packaged in a sterile wrapping with a lens placed in the jaws. Therefore, the physician need not expose the holder or the lens to potentially destructive sterilization procedures immediately prior to implantation. Alternatively, the holder may be packaged as a separate unit.

The above-mentioned purposes and operations of the invention are more readily apparent when read in conjunction with the following description of the drawings, and the detailed discussion of the preferred embodiment of the present invention.

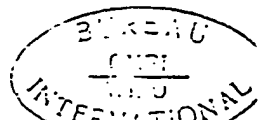
Brief Description of the Drawings

FIGURE 1 is a top plan view of the forceps of the invention showing the jaws in an open position;

FIGURE 2 is a top plan view of the apparatus of FIGURE 1 with the jaws shown in a closed position;

FIGURE 3 is a cross-sectional view of the apparatus of FIGURE 2 taken along line A-A'; and

FIGURE 4 is a side view of the apparatus of FIGURE 1.



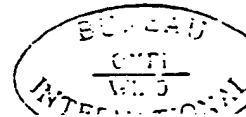
- 8 -

Detailed Description of the Drawings

FIGURES 1 through 4 show the preferred embodiment and best mode of the invention. The lens holder, generally indicated at 10, comprises a pair of opposed jaws 12, a fulcrum 14 separating the jaws 12, and an extension 18 of each of the two jaws 12 extending away from the fulcrum 14. The two jaw extensions 18 meet to form handle 22 at an integral connection 19. The extensions 18 meet at a distance from fulcrum 14 which ranges from 1.25 to 1.75 inches and is preferably 1.375 inches. Thus, the two extensions 18 are separated from each other allowing finger pressure on the jaw extensions 18 to push the jaw extensions 18 toward each other into contact with one another.

The face of each opposing jaw 12 defines an arcuate slot 16, the radius of which corresponds to the radius of the intraocular lens intended to be held by the jaws 12. When the jaws 12 are in their normal closed position as is illustrated in FIGURE 2, a typical intraocular lens 20 may be held securely within the slots 16 of the jaws 12 without pressure on the lens 20. FIGURE 3 shows a cross-section of the jaws 12 and lens 20 taken at line A-A' of FIGURE 2, and shows that the portion of the jaws 12 which surround the slots 16 and the lens 20 prevents the lens 20 from moving to the right or to the left. Referring again to FIGURE 2, the mouth 13 of jaws 12 is normally open less than the diameter of lens 20, so that lens 20 may not fall out of the mouth.

FIGURE 1 shows the manner in which the lens 20 may be released from the jaws 12 when the lens is placed within the eye during a surgical operation. The jaw extensions 18 are depressed by finger pressure toward one another and may contact one another. Pressure on jaw extensions 18 rotates the jaws 12 around fulcrum



- 9 -

14, thus moving the slots 16 away from lens 20 and enlarging the mouth between jaws 12 so that the diameter of lens 20 is less than the width of the mouth. Contact of the jaw extensions 18 against each other affords positive feedback to the surgeon that the lens has been released, and is not damaging to the lens 20 or the lens holder 10. Positive feedback of this sort is extremely valuable to a physician in surgical procedures such as intraocular lens placement where both the lens and the tissues involved are small, and the physician's ability to view the surgical site is limited.

Contact of the jaw extensions 18 also prevents jaws 12 from opening so wide as to damage sensitive eye tissue through which the lens holder 10 is moved during surgery.

FIGURE 4 shows the angle at which the jaws 12 are mounted with respect to the jaw extensions 18 and handle 22. The placement of jaws 12 at an acute angle to the line of jaw extensions 18 and handle 22 allows the physician to maneuver more accurately within the confines of the human eye than would a straight lens. This angle preferably falls within the range of ten degrees to fifty degrees. The angled construction allows placement of the lens without prying either the cornea or the iris during its insertion.

The lens holder is typically formed by injection molding of a thermoplastic which is rigid or semi-rigid and sufficiently flexible to allow jaw and extension movement in the shape and size required. Such plastics include high density polyethylene, polypropylene, filled or unfilled polyacetyl, polystyrene, ABS polymers and nylon. In the preferred embodiment, the lens holder is made of fiberglass-filled polyacetyl. These materials give maximum strength with minimal volume, and allow

- 10 -

the jaw extensions 18 to resist normal finger pressure and prevent accidental opening of the jaws. Thus, the lens holder thus gives the maximum finger control and requires sufficient force to open the jaws while being
5 easy to manipulate with respect to rotation. Furthermore, the constructional distances of the lens holder are such that magnification of movement does not occur.

Typically, the lens holder 10 is sterilized immediately after manufacture and then packaged in an
10 air-tight plastic envelope wrapper with a sterilized lens 20 placed between jaws 12. This enables the physician to avoid the step of placing or grasping a lens 20 within jaws 12 of the lens holder which could allow the lens to pop out of the holder in an undesirable location or
15 cause damage to the lens. However, there may be surgical situations in which it is desirable to have the lens holder 10 packaged separately from the lens 20.

While the preferred embodiment of the invention has been disclosed, it is understood that the invention
20 is not limited to such an embodiment, since it may be otherwise embodied in the scope of the appended claims.



- 11 -

What is Claimed is:

1. An intraocular lens holder comprising first and second jaw members, a fulcrum, and a handle; each of said first and second jaw members being attached to said fulcrum and spaced apart from one another, said jaw members being adapted to selectively hold and release a lens, said handle comprising first and second extensions of said first and second jaw members connected together, said extensions being substantially identical to each other and spaced apart from one another for a predetermined distance from said fulcrum, said extensions being united at a distance from said fulcrum.

2. A lens holder as claimed in claim 1, wherein said extensions are united at a distance from said fulcrum ranging from 1.25 to 1.75 inches.

3. A lens holder as claimed in claim 2, wherein said extensions are united at a distance from said fulcrum of 1.375 inches.

4. A lens holder as claimed in claim 1 wherein each of said first and second jaw members define an inner face, said inner faces of said first and second jaw members being spaced apart a distance less than the diameter of an intraocular lens, each of said inner faces further defining an arcuate slot adapted to hold said intraocular lens.

5. A lens holder as claimed in claim 4, wherein said extensions are flexible allowing them to be squeezed toward one another thereby moving said first and second

- 12 -

jaw members apart from one another to release said intra-ocular lens.

6. A lens holder as claimed in claim 5 wherein said extensions are flexibly moveable to contact one another between said fulcrum and an integral end connector means, said contact area forming a stop to limit the maximum separation of said first and second jaw members.

7. A lens holder as claimed in claim 1, wherein said first and second jaw members intersect a line drawn through the axis of said extensions to define an acute angle.

8. A lens holder as claimed in claim 7, wherein said acute angle ranges from ten degrees to fifty degrees.

9. A lens holder as claimed in claim 1, wherein said lens holder is an integrally formed apparatus.

10. A lens holder as claimed in claim 4, wherein said jaw members are curved toward each other so that the distance between the ends of the jaw members is less than the diameter of the lens.

11. An intraocular lens holder comprising first and second jaw members, a fulcrum, and a handle; each of said first and second jaw members being attached to said fulcrum and spaced apart from one another, each of said first and second jaw members defining an inner face, said inner faces of said first and second jaw members being spaced apart a distance less than the diameter of an intraocular lens, each of said inner faces further defining a channel adapted to hold said intraocular lens,



- 13 -

said handle comprising first and second extensions of said first and second jaw members, said extensions having at least some portions spaced apart from one another, and extending away from said fulcrum a distance ranging from 1.25 to 1.75 inches, said extensions being connected together at a distance from said fulcrum and defining an angle with said jaw members.

12. An apparatus as claimed in claim 4, wherein said arcuate slots are of a radius equal to the radius of an intraocular lens.

13. An intraocular lens implantation apparatus comprising a packaged intraocular lens and a lens holder, said lens holder comprising first and second jaws, a fulcrum, and a handle; said jaws being spaced apart a distance less than the diameter of said intraocular lens, each of said jaws defining an inner face, each of said inner faces further defining a slot to hold said intraocular lens; each of said jaws being connected to said fulcrum and having an extension beyond said fulcrum to form said handle, each of said extensions being spaced apart from one another for a predetermined distance and joined together by connecting means, said extensions being adapted to be pressed together to open said first and second jaw members to release said intraocular lens, said extensions having inner surfaces which act as limiting means to limit the outward extension of said opened jaw members.

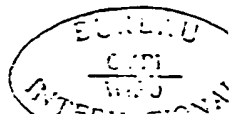
14. An apparatus as claimed in claim 13, wherein said first and second jaw members and said extensions define an acute angle in the range of ten degrees to fifty degrees.

- 14 -

15. An apparatus as claimed in claim 13, wherein said extensions extend from said fulcrum a distance of 1.25 to 1.75 inches before being connected together.

16. An apparatus as claimed in claim 13, wherein said extensions are adapted to contact each other to limit the maximum opening of said first and second jaws.

17. An apparatus as claimed in claim 13, wherein said slots are arcuate and surround edge portions of said intraocular lens to prevent said lens from escaping said jaws which are curved toward each other.



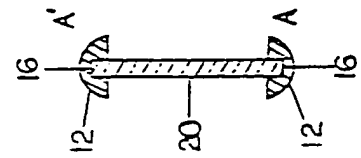
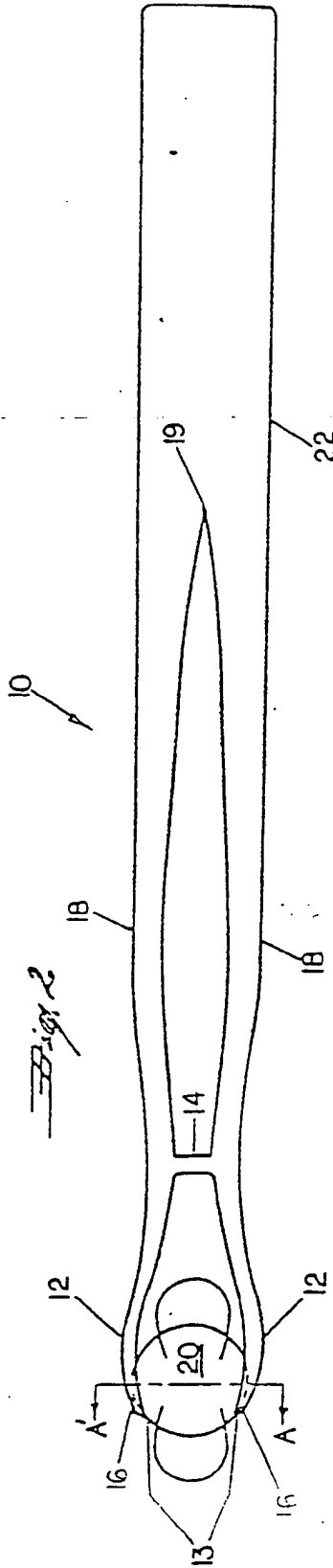
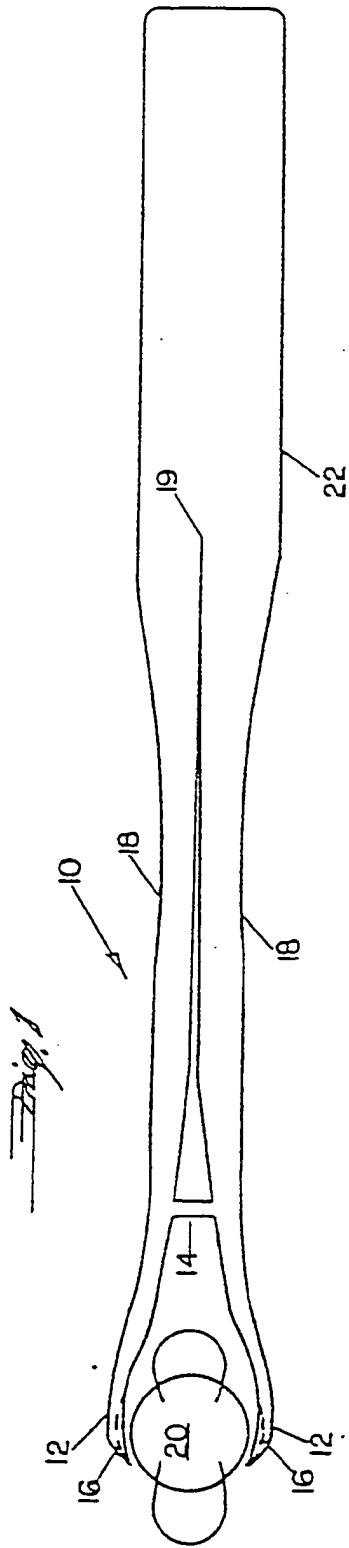


Figure 3

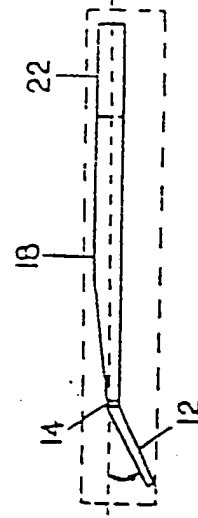


Figure 4

INTERNATIONAL SEARCH REPORT

International Application No PCT/US81/01509

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. ³	A61B	17/30
U.S. Cl.	128/354	
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System ¹	Classification Symbols	
U.S.	128/354, 321, 303R; 294/ICA, 33, 99R; 81/43	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	US, A, 3,817,078, Published 18 June 1974, REED ET AL	1-17
X	US, A, 4,198,980, Published 22 April 1980, . CLARK	1-17
* Special categories of cited documents: ¹⁵		
"A" document defining the general state of the art "E" earlier document but published on or after the international filing date "L" document cited for special reason other than those referred to in the other categories "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but on or after the priority date claimed "T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention "X" document of particular relevance		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ¹		Date of Mailing of this International Search Report ²
26 January 1982		12 FEB 1982
International Searching Authority ¹		Signature of Authorized Officer ²
ISA/US		MICHAEL THALER